EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

19 December 2016

(Substance evaluation – PBT assessment – Endocrine disruption – Proportionality – Annex XIII – Article 47 – Article 130 – Animal welfare)

Case number	A-018-2014
Language of the case	English
Appellant	BASF Grenzach GmbH, Germany
Intervener	PETA International Science Consortium Ltd., United Kingdom
Contested Decision	Decision of 19 September 2014 on the substance evaluation of triclosan, adopted by the European Chemicals Agency pursuant to Article 46(1) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p.1; corrected by OJ L 136, 29.5.2007, p. 3) (hereinafter the 'REACH Regulation') The Decision was notified to the Appellant through the annotation number SEV-D-2114285478-33-01/F

THE BOARD OF APPEAL

composed of Mercedes Ortuño (Chairman), Andrew Fasey (Technically Qualified Member and Rapporteur) and Rafael López Parada (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

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Background to the dispute

1. The Appellant is the registrant of the substance triclosan (hereinafter 'triclosan' or the 'Substance'), a broad-spectrum antibacterial commonly used in dentifrices, soap and other consumer products.

2. This appeal is directed against a substance evaluation decision adopted by the European Chemicals Agency (hereinafter the 'Agency') pursuant to Article 46(1) of the REACH Regulation (all references to Articles and Annexes hereinafter concern the REACH Regulation unless stated otherwise).

3. The Substance was included in the Community rolling action plan (CoRAP) for evaluation in 2012 due to initial grounds for concern relating to its persistent, bioaccumulative and toxic (hereinafter 'PBT') properties as well as its potential for endocrine disruption.

4. The Competent Authority of the Netherlands (hereinafter the 'eMSCA') was appointed to carry out the evaluation, in cooperation with the Competent Authority of Denmark.

5. The eMSCA prepared a draft decision pursuant to Article 46(1) requesting further information on the Substance (hereinafter the 'Draft Decision'). The Draft Decision was notified to the Appellant in accordance with Article 50(1) on 20 March 2013.

6. The Appellant duly commented on the Draft Decision on 23 April 2013. The eMSCA considered those comments and revised the Draft Decision. The revised Draft Decision was notified to the Competent Authorities of the other Member States (hereinafter 'MSCAs') and to the Agency on 6 March 2014 for the submission of proposals for amendment pursuant to Article 51(2) in conjunction with Article 52(2). Four MSCAs and the Agency submitted proposals for amendment.

7. The eMSCA reviewed the proposals for amendment and amended the Draft Decision. The amended Draft Decision was referred to the Member State Committee (hereinafter the 'MSC') on 22 April 2014.

8. In accordance with Article 51(5) in conjunction with Article 52(2), the Appellant provided comments on those proposals, which were considered by the MSC.

9. The MSC reached a unanimous agreement on 12 June 2014. The Contested Decision was adopted by the Agency on 19 September 2014.

10. The Contested Decision requires the Appellant to submit to the Agency certain information on exposure as well as information addressing PBT concerns, concerns on endocrine disruption and concerns regarding cardiotoxicity. Section II of the Contested Decision, entitled '*Information required*', is worded as follows:

> *'[i] Concerns on persistency, bioaccumulation and toxicity (PBT)*
>
> *Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test method(s) and the registered substance subject to the present decision:*
>
> *1. Simulation testing of Triclosan on ultimate degradation in fresh surface water (lake or river) and sea water performed as pelagic test (i.e. water only without addition of suspended solids) at an environmentally relevant temperature of at most 12 degrees centigrade […] (test method: EU C.25/OECD [test guideline, hereinafter 'TG'] 309). The test set up shall enable to check the mass balance (using radiolabelled Triclosan) and the identification of transformation products relevant for PBT assessment (at a concentration of 0.1 % w/w unless it can be demonstrated that this is technically not possible).*

[ii] Concerns on endocrine disruption

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

2. Enhanced Developmental Neurotoxicity Study (test method: OECD TG 426 with relevant elements of Extended One-Generation Reproductive Toxicity Study, OECD TG 443).

The proposed study has the basis in the oral OECD TG 426 design, but shall additionally include several endpoints which are mandatory in the extended one generation study (OECD TG 443). Therefore, the OECD TG 426 study with oral gavage dosing during pregnancy and early lactation until direct dosing of the pups starts, shall also include measurements in the offspring of: anogenital distance, weight and histopathology of reproductive organs and include a quantitative evaluation of primordial and small growing follicles, as well as corpora lutea, estrous cyclicity and semen quality, as detailed in the OECD TG 443. Furthermore direct dosing of the pups is requested and offspring shall be exposed directly during the entire postnatal period, i.e. from the 3rd or 4th day after birth until weaning. When using direct dosing of pups, it may in the beginning of the dosing period for practical reasons be necessary to use a micropipette for administering Triclosan solution into the mouth of the offspring. Exposure shall continue using oral gavage when the size of the pups allows for this procedure to be used.

The study shall furthermore be performed in Wistar rats and the dose levels for the dams shall be 30, 100 and 300 mg/kg bw/day. For the direct dosing of the offspring the dose level shall be 15, 50 and 150 mg/kg bw/day using a dosing procedure and a dosing solution volume in e.g. corn oil, in accordance with paragraph 30 of OECD TG 443 and with a dosing volume as low as possible, in accordance with good animal welfare practice. If the Registrant(s) need to perform a range-finding study and results from such a study should indicate the need for modifying the proposed dose levels, this may be acceptable provided that robust scientific justification is given.

The study shall also include additional measurements of Thyroxine (T4) in all the dams during gestation, preferably around gestation day (GD) 15. All blood sampling shall be performed to minimize animal distress. A possibility is blood sampling from the tongue of the pregnant rats without anaesthesia, a method which has the advantage that potential animal loss because of use of anaesthesia is avoided. Should the performing laboratory however prefer to use another procedure for obtaining blood samples from pregnant dams, this shall be done in a way to minimize animal distress as mentioned above. 1-2 pups per litter shall be sacrificed for blood sampling and their trunk blood shall be used for the thyroid hormone measurements. The blood for measurements of T4 levels in the offspring shall be taken at a point in time when they are being directly dosed, preferable between prenatal development day (PND) 10 and 14. This sample shall be retrieved to make sure that the offspring have been exposed enough to Triclosan in the postnatal period to lower their T4 levels, which may cause behavioral effects later in life.

3. Fish Sexual Development Test (FSDT, test method: OECD TG 234) with zebrafish or Japanese medaka.

The nominal test (target) concentrations shall, based on available existing information, be set at exposure concentrations of 15, 50 and 150 µg/l in a flow through system unless scientific evidence indicates that other exposure concentrations are more appropriate. The actual exposure concentrations shall be verified analytically as specified in the test guideline.

The study shall include the optional endpoints of the test guideline, i.e. gonadal histopathology (evaluation and staging of oocytes and spermatogenetic cells) to be able to characterize and better address any effects seen on sperm counts. If medaka is used also the genetic sex and secondary sex characteristics should be reported.

[…]

[iii] Concerns regarding cardiotoxicity

4. Available information on the effects of Triclosan on the cardiovascular system, including information on blood pressure, heart rate, electrocardiogram and human vigilance […].

[iv] Concerns regarding exposure

5. Further information on the environmental emission scenario "Wide dispersive indoor use of reactive substances in open systems" […].'

11. The deadline set for the submission of the required information was 26 September 2016.

Procedure before the Board of Appeal

12. The Appellant filed this appeal on 17 December 2014.

13. The Agency filed its Defence on 2 April 2015.

14. On 16, 17 and 18 March 2015 respectively, the Swedish Chemicals Agency (KEMI), PETA International Science Consortium Ltd (PISC) and the European Coalition to End Animal Experiments (ECEAE) sought leave to intervene in these proceedings.

15. The applications submitted by KEMI and the ECEAE were dismissed by separate decisions of 29 September 2015. PISC was granted leave to intervene in support of the Appellant by decision of 6 October 2015.

16. Following consultation with the parties, the proceedings were stayed between 1 June and 1 September 2015.

17. On 14 September 2015, since the position of legally qualified member of the Board of Appeal was vacant and in order to achieve the full composition of the Board of Appeal, the Chairman, pursuant to the first subparagraph of Article 3(2) of Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5; hereinafter the 'Rules of Procedure'), designated an alternate member, Rafael López Parada, to act in the present case as the legally qualified member of the Board of Appeal.

18. The Appellant provided observations on the Defence on 23 November 2015.

19. The Intervener submitted its observations on 12 January 2016.

20. On 28 January 2016, the Agency filed its observations on the Appellant's observations on the Defence.

21. The Agency and the Appellant submitted observations on the Intervener's observations on 22 February 2016.

22. The written procedure was closed on 24 March 2016. In view of the Appellant's and the Agency's requests for a hearing to be held, and pursuant to Article 13 of the Rules of Procedure, the parties were summoned to a hearing which was held on 9 June 2016. At the hearing, the Appellant and the Agency made oral submissions and responded to questions from the Board of Appeal.

Forms of order sought

23. In its Notice of Appeal the Appellant requests the Board of Appeal to:

- Modify the Contested Decision insofar as it requires the Appellant to perform simulation testing of triclosan on ultimate degradation in fresh surface water (lake or river) and sea water performed as pelagic test (i.e. water only without addition of suspended solids) at an environmentally relevant temperature of at most 12 degrees centigrade (OECD TG 309; hereinafter the 'persistence testing'), by allowing the Appellant to perform the test on surface marine water with additional suspended solids/sediment of 0.01 to 1 g/L dry weight, as set out as an optional approach in OECD TG 309;
- Annul the Contested Decision in so far as it requires the Appellant to perform an enhanced developmental neurotoxicity study (OECD TG 426 with relevant elements of an extended one-generation reproductive toxicity study in accordance with OECD TG 443; hereinafter the 'enhanced developmental neurotoxicity study');
- Annul the Contested Decision in so far as it requires the Appellant to perform a fish sexual development test (OECD TG 234; hereinafter the 'fish sexual development test');
- Annul the Contested Decision in so far as it obliges the Appellant to submit available information on the effects of the Substance on the cardiovascular system; and
- Order the refund of the appeal fee.

24. The Intervener contends that the Board of Appeal should:

- Annul the Contested Decision in so far as it requires the Appellant to perform the enhanced developmental neurotoxicity study; and
- Annul the Contested Decision in so far as it requires the Appellant to perform the fish sexual development test.
- In the alternative, if the Board of Appeal does not annul the Contested Decision insofar as it requires the Appellant to perform an enhanced developmental neurotoxicity study, '*consideration should be given*' to minimising the distress caused to rats during the course of testing, in particular by means of anaesthesia before blood sampling, by dosing offspring orally with a micropipette and by considering alternatives to oral gavage for pups.

25. The Agency requests the Board of Appeal to dismiss the appeal as unfounded.

Reasons

26. The Appellant raises several pleas in law in relation to each of the contested requests for information, alleging that the Agency breached various provisions of the REACH Regulation and contravened the relevant guidance documents, breached the principle of proportionality and the principle of good administration.

27. The Appellant's pleas in law will be examined in relation to each of the contested requests for information.

I. The first request for information, concerning persistence testing

28. The Appellant raises five pleas in law against the Contested Decision in so far as it requires persistence testing, namely (i) breaches of Annex XIII and contravention of the Agency's Guidance on information requirements and chemical safety assessment, Version 1.2 (November 2012; hereinafter the 'Guidance') as well as breaches of (ii) Article 47, (iii) Article 130, (iv) the principle of proportionality and (v) the principle of good administration.

A - Admissibility

29. In its Notice of Appeal, the Appellant requests the Board of Appeal to '*[m]odify the Contested Decision insofar [as] it obliges the Appellant to conduct the persistency testing and permit the Appellant to conduct in its place the OECD 309 test as surface marine water amended with suspended solids/sediment […]*' (emphasis added). At the hearing, however, the Appellant claimed that this form of order is '*not correct*'. It stated that it seeks the amendment of the Contested Decision to the effect that it may perform the test using '*surface freshwater amended with suspended solids/sediment […]*' (emphasis added).

30. The Board of Appeal observes, in this regard, that the form of order sought by the Appellant as explained at the hearing concerns a crucial aspect of the case, namely the proportionality of the measure (fourth plea). The form of order put forward at the hearing is substantively different from the one set out in the Notice of Appeal and is consequently new.

31. The Board of Appeal also notes that, pursuant to Article 6(1)(d) of the Rules of Procedure, the Notice of Appeal must contain the remedy sought by the Appellant. Moreover, under Article 12(2) of the Rules of Procedure, no new plea in law, and a fortiori no new form of order, may be introduced after the first exchange of written pleadings unless it is based on new matters of law or of fact that come to light in the course of the proceedings (see, to that effect and by analogy, Case T-675/13, *K Chimica* v *ECHA*, EU:T:2016:480, paragraph 21, and Case T-24/00, *Sunrider* v *OHIM (VITALITE)*, EU:T:2001:34, paragraph 12).

32. In the present case, the Appellant has not indicated which new matters of law or of fact have arisen to justify the new form of order. It follows that the form of order put forward by the Appellant at the hearing is inadmissible. The Board of Appeal will therefore decide on the form of order stated in the Notice of Appeal (see paragraph 23 above, first indent).

B - The first plea, alleging a breach of Annex XIII and a contravention of the Guidance

Arguments of the parties

33. By its first plea in law, the Appellant argues that Annex XIII requires that the information used for the purposes of assessment of the PBT or very persistent and very bioaccumulative (hereinafter 'vPvB') properties of a substance '*shall be based on data obtained under relevant conditions*'.

34. The Appellant further relies on Section C.1.4.1 of the Guidance, which states that '*[i]f persistency cannot be excluded, it should be determined which compartments are likely to be exposed, and hence which simulation tests need to be conducted.*

This determination of the compartments(s) [sic] for simulation testing should take account of the intrinsic properties of the substance (e.g. water solubility, vapour pressure, log Kow, Kp, Koa, half-life in air) that are significantly influencing the environmental fate of the substance.'

35. The Appellant takes the view that Annex XIII and the Guidance '*confirm that the objective of substance evaluation is to gain a realistic assessment of the substance's behavior under environmentally relevant conditions. Risk assessment should likewise be conducted in a way reflecting real life circumstances as closely as possible*.' Therefore, the required testing must '*tak[e] into account the most relevant environmental compartments and the rate at which [the Substance] partitions into those compartments*'.

36. The Appellant argues in this regard that the direct emission of sewage treatment plant effluents into surface water is the most important source of emission of the Substance into the environment and that the situations in which the Substance can be detected in pure fresh or sea water are '*extremely rare*'. It proposes an alternative testing strategy, set out as an option in OECD TG 309, namely testing on surface marine water with additional suspended solids/sediment (0.01 to 1 g/L dry weight), which would generate more useful data for the assessment of the persistence of the Substance. The Appellant claims that the Agency '*failed to assess*' this alternative testing strategy.

37. The Appellant also relies on an expert statement which it commissioned after the adoption of the Contested Decision and which it attached to the Notice of Appeal. According to the Appellant, this expert statement confirms that the proposed alternative testing strategy would enable an assessment of the adsorption of the Substance and reflect more accurately its behaviour in the environment.

38. In the Appellant's view, therefore, the Contested Decision specifies testing conditions that do not adequately reflect the environmental distribution of the Substance and consequently do not constitute '*relevant conditions*' within the meaning of Annex XIII and of the Guidance. By requiring testing to be conducted in compartments in which the Substance is the least likely to be detected, namely pelagic marine and fresh water, and where it cannot demonstrate its dissipation behaviour, the Agency therefore breached Annex XIII and acted inconsistently with the Guidance.

39. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

40. The Appellant claims, in essence, that the testing conditions required by the Contested Decision are not '*relevant*' within the meaning of Annex XIII.

41. The fourth introductory paragraph of Annex XIII provides that '*[t]he information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*'. The Board of Appeal will therefore examine whether the testing conditions prescribed by the Contested Decision, namely testing in pelagic waters without additional suspended particulate matter, constitute '*relevant conditions*' within the meaning of the fourth introductory paragraph of Annex XIII.

42. The Board of Appeal observes, in this regard, that Section III of the Contested Decision, entitled 'Statement of reasons', refers to a wealth of information, in particular previous persistence tests in soil and water/sediment systems, which indicates that the Substance may be persistent. In particular, the half-life of the

Substance has been found to approach and sometimes exceed the criteria for a finding of persistence in some soil and water/sediment studies.

43. It must also be noted that, as both parties agree, the Substance quickly binds with suspended particulate matter, and is therefore partially eliminated from the water phase in water-sediment systems. There are, however, no existing data on the persistence of the Substance in pelagic water. As the Agency explained at the hearing in response to a question from the Board of Appeal, the results of testing in water-sediment systems do not allow a conclusion to be drawn as to the half-life of the Substance in pelagic water. The Appellant did not dispute this point.

44. Furthermore, the Appellant does not dispute that, as stated in the Contested Decision, the Substance has been detected in numerous monitoring studies conducted on large freshwater bodies such as the Great Lakes in North America, large Swiss lakes and European rivers. The Substance has also been detected in numerous marine waters including the German Bight, Victoria Harbour in Hong Kong, Charleston Harbour and estuary, the Southern California Bight, coastal waters around Singapore, Greenwich Bay, the Lower Hudson estuary, and mangroves in India. As the Agency points out, and the Appellant does not dispute, such water bodies do not contain large quantities of the suspended particulate matter with which the Substance readily binds.

45. The evidence therefore shows that the Substance is present in both fresh and marine pelagic waters and that it is potentially persistent in such waters.

46. The Appellant argues that the direct emission of sewage treatment plant effluents into surface water, which may or may not contain high levels of solids or sediment, is the most important source of emission of the Substance into the environment. In the Appellant's view, testing in pelagic water without additional suspended particulate matter does not constitute '*relevant conditions*' within the meaning of the fourth introductory paragraph of Annex XIII.

47. The Board of Appeal observes that Section 12.2 of Annex II defines persistence as '*the potential for the substance […] to degrade in the environment, either through biodegradation or other processes, such as oxidation or hydrolysis*'. Persistence is therefore determined on the basis of the potential of the substance to degrade in the environment, not on the basis of the actual behaviour of the substance in particular environmental conditions (see, by analogy, Case A-013-2014, *BASF*, Decision of the Board of Appeal of 7 December 2016, paragraphs 112 and 113).

48. The Board of Appeal also observes that Section 1.1.1 of Annex XIII identifies the compartments that are relevant to the assessment of whether a substance is persistent. In accordance with that provision, '*[a] substance fulfils the persistence criterion (P) in any of the following situations:*

    (a) the degradation half-life in marine water is higher than 60 days;

    (b) the degradation half-life in fresh or estuarine water is higher than 40 days;

    (c) the degradation half-life in marine sediment is higher than 180 days;

    (d) the degradation half-life in fresh or estuarine water sediment is higher than 120 days;

    (e) *the degradation half-life in soil is higher than 120 days*.'

49. There is nothing in Section 1.1.1 of Annex XIII to suggest that the '*relevant conditions*' for the assessment of persistence must be limited to the most frequent patterns of distribution of a substance in the environment. Section 1.1.1 of Annex XIII requires that information generated in '*any*' of the above compartments can be used to assess the persistence of a substance. This does not preclude testing for persistence in multiple compartments if it is necessary to do so.

50. Indeed, the objective of the persistence testing in this particular case is not to assess the behaviour of the Substance under what the Appellant terms '*environmentally relevant conditions*', meaning in waters with a high content of suspended solids or sediment. The objective is, instead, to determine the degradation half-life of the Substance in specific compartments (namely pelagic fresh and marine water) without the formation of large amounts of bound residue, which would hamper the interpretation of the results of the study, in order to determine whether the Substance is persistent in the two compartments identified.

51. Pursuant to substance evaluation and in light of the potential concerns identified in this particular case, the testing conditions prescribed by the Contested Decision are consequently relevant to the assessment of the persistence of the Substance with regard to the marine and freshwater compartments. The Appellant's first plea must therefore be rejected.

C - The second plea, alleging a breach of Article 47

Arguments of the parties

52. By its second plea in law the Appellant claims that the Contested Decision was adopted in breach of Article 47.

53. Article 47 provides that the evaluation of a substance must be based on all relevant information submitted on that substance. The Appellant alleges that the Agency did not take into account certain relevant information on the behaviour of the Substance in the environment contained in the registration dossier. In particular, according to the Appellant, the Agency failed to take into account the fact that the Substance is largely eliminated from wastewater by sewage treatment plants, not only by adsorption but also by mineralisation, and that the Substance rapidly dissipates from the water phase and adsorbs into sediment, which indicates '*a relatively high potential for removal from the water compartment*'. Moreover, the Agency allegedly '*ignored […] all of the monitoring data which are available*'.

54. The Appellant argues moreover that, in accordance with Annex XIII, assessment of the persistence of a substance is based on a weight-of-evidence determination. Such a weight-of-evidence determination in turn requires all relevant and available information, including the results of environmental monitoring information and the quality and consistency of data, to be considered. In addition, the Appellant points out that Section R.7b of the Guidance provides that '*[k]nowledge of bound residues and incorporation into biomass also needs to be considered and should be seen as a potential removal pathway*'.

55. The Agency should therefore have taken into account the information on the removal of the Substance from the water compartment when evaluating the Substance under Article 47. The Agency did not take '*sufficient account'* of the information on adsorption to sediment as a relevant removal pathway. In particular, it '*should have recognized that Triclosan rapidly dissipates in the water phase and adsorbs to sediment because the formation of bound residues significantly reduces Triclosan's bioaccessibility and bioavailablity. This process takes place not only in shallow waters but also in the water column with suspended particular [sic] matter. [The Substance] will partition in the aquatic environment (similar to partitioning in [sewage treatment plants]), and this should be considered when interpreting the presence of the substance in [sewage treatment plant] effluent as an indication of persistency in the aqueous compartment.*'

56. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

57. The Appellant claims that the Agency breached Article 47 by failing to take into account certain information contained in the registration dossier, namely information concerning the fact that the Substance is largely eliminated from wastewater by sewage treatment plants and that it rapidly binds with suspended particulate matter and is consequently eliminated from the water phase to a large extent.

58. The Board of Appeal observes that, according to Article 47, *'[a]n evaluation of a substance shall be based on all relevant information submitted on that particular substance'.* Whilst the Agency must examine this information carefully and impartially, this does not mean that it will necessarily arrive at the same conclusions as a registrant.

59. First, with regard to the Appellant's argument that the Substance is largely eliminated from wastewater by sewage treatment plants the Board of Appeal notes that that this argument is a repetition of a point raised in the Appellant's comments on the Draft Decision. The Contested Decision answers the Appellant's argument as follows:

'*The eMSCA accepted that a large fraction of Triclosan is removed in the sewage treatment plant […]. Despite this, [sewage treatment plants] do not remove all Triclosan and as a result, [they] are the most important source for emission of Triclosan (and of methyl Triclosan) to the aquatic environment. Due to its wide dispersive use, monitoring studies report Triclosan in relatively high concentrations in effluents of [sewage treatment plants] and in receiving surface waters, where degradation is suspected to be much lower: Triclosan appears to be a ubiquitous substance in fresh surface waters all over the world. […]*.'

60. In addition, the Contested Decision states that '*Triclosan is released via the effluents of sewage treatment plants into rivers and other receiving water bodies […and] concentrations in the marine environment are still relatively high*'.

61. The sections of the Contested Decision quoted in paragraphs 59 and 60 above show that the Agency did take into account the fact that the Substance is largely eliminated in sewage treatment plants. However, it is clear that the Agency did not agree with the inferences which the Appellant drew from that fact. The Appellant's argument that the Agency failed to take this information into account must therefore be dismissed.

62. Second, as regards the Appellant's argument that the Agency failed to take into account relevant information showing that the Substance rapidly binds with suspended particulate matter and is consequently eliminated from the water phase to a large extent, the Board of Appeal notes that this argument is also a repetition of a comment on the Draft Decision. In the Contested Decision, the Agency replied to the Appellant's comments concerning the dissipation of the Substance in the following terms:

'*The half-life of Triclosan in water from a water-sediment study (OECD TG 308) only reflects dissipation due to fast sorption to the sediment in such a system. It cannot be used to compare with the P/vP Criteria for surface water that are clearly defined for degradation (Commission Regulation (EU) No 253/2011) and not for dissipation. Consequently, the degradation in an OECD TG 308 test is not a measure of degradation in the pelagic water column, but of degradation in the sediment instead, often reflecting anaerobic degradation.*

Besides that, the interpretation of the available OECD TG 308 study is hampered by the fact that bound residue is formed to a high degree. The obtained half-lives

therefore reflect dissipation rather than degradation. This effect is also observed for soil, for which a large discrepancy in half-lives exists between field studies or studies with Triclosan incorporated in activated sludge on the one hand and soil freshly spiked with Triclosan in the available OECD TG 307 study on the other hand.'

63. The Contested Decision therefore explicitly and extensively discusses the information provided by the Appellant concerning the dissipation behaviour of the Substance. In these circumstances, the Appellant's second argument cannot prosper.

64. In addition, as regards the Appellant's argument that the assessment of the persistence of a substance is based on a weight-of-evidence approach, the Board of Appeal observes that, in accordance with Annex XI, such an approach can be used to adapt standard information requirements for registration purposes. However, pursuant to substance evaluation, provided that the Agency correctly exercised its discretion, in particular by taking into account all relevant information submitted on a substance, further information can be requested to clarify a potential concern even if a weight-of-evidence adaptation has been applied for registration purposes. Consequently, the Appellant's argument must be dismissed.

65. For these reasons, the Appellant's second plea must be rejected.

D - The third plea, alleging a breach of Article 130

Arguments of the parties

66. By its third plea in law the Appellant argues that the Contested Decision does not satisfy the requirements of the duty to state reasons.

67. The Appellant alleges that the Agency has failed to explain why it has not considered the alternative OECD 309 suspended sediment test proposed by the Appellant. In the Appellant's view, in circumstances in which it had consistently maintained that pelagic water is not an appropriate compartment as it does not contain sediment, the Agency was obliged to explain why, despite having a choice, it requested the pelagic tests without addition of any suspended solids/sediment.

68. In addition, the Appellant alleges that the reasoning in the Contested Decision is confusing in so far as it states that '*[t]he pelagic test (OECD TG 309) uses natural water, which includes suspended particular matter that is naturally present in the water column. Any effects of partitioning between this suspended particular matter and the dissolved phase on the fate of Triclosan will thus be dealt with in this type of simulation test*'.

69. The Agency contends that the Contested Decision is adequately reasoned.

Findings of the Board of Appeal

70. In accordance with Article 130, all decisions taken under the REACH Regulation must be reasoned. The case-law on the duty to state reasons under Article 296 of the Treaty on the Functioning of the European Union is applicable to Article 130 (see Case A-001-2012, *Dow Benelux*, Decision of the Board of Appeal of 19 June 2013, paragraph 87).

71. In accordance with that case-law, the statement of reasons must be appropriate to the act at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in question in such a way as

to enable the persons concerned to ascertain the reasons for the measure and to enable the courts to exercise their powers of review (see Joined Cases C−239/11 P, C−489/11 P and C−498/11 P, *Siemens and Others* v *Commission*, EU:C:2013:866, paragraph 392; see also, to that effect, Case A-006-2014, *International Flavors & Fragrances*, Decision of the Board of Appeal of 27 October 2015, paragraph 110; Case A-004-2014, *Altair Chimica and Others*, Decision of the Board of Appeal of 9 September 2015, paragraph 127).

72. First, with regard to the Appellant's argument that the Contested Decision fails to explain the reasons for the rejection of its proposed addition of suspended particulate matter to the water used for testing, in accordance with an optional approach under OECD TG 309, the Board of Appeal observes that the Appellant did not in fact propose such a study during the course of the substance evaluation procedure. It confined itself to stating that, taking the existing information into account, '*Triclosan cannot be regarded a [sic] persistent (P) or very persistent (vP) according to the current PBT/vPvB criteria and thus there is no need for further environmental fate testing on Triclosan*'. The Appellant's comment therefore related to the existence of a potential concern and not to the test to be conducted to clarify that concern. The Appellant's argument must consequently be rejected.

73. Second, insofar as the Appellant argues that the Contested Decision fails to explain why, despite having a choice, the Agency required testing in pelagic waters without additional suspended particulate matter, the Board of Appeal observes that the Contested Decision does in fact deal with this issue at considerable length (see the sections quoted in paragraphs 59, 60 and 62 above). This argument must therefore also be rejected.

74. Third, the Appellant argues that the statement of reasons is '*confusing*' in so far as it provides that '*[t]he pelagic test (OECD TG 309) uses natural water, which includes suspended particular [sic] matter that is naturally present in the water column. Any effects of partitioning between this suspended particular matter and the dissolved phase on the fate of Triclosan will thus be dealt with in this type of simulation test*'. However, the Board of Appeal observes that the Appellant has not substantiated this argument. In any event, without there being a need to consider the accuracy of this statement, the Board of Appeal observes that the wording of the Contested Decision is quite clear. Therefore the argument cannot prosper.

75. For the sake of completeness, the Board of Appeal also observes that the Contested Decision is not contradictory in so far as it requires a pelagic test without added solids/sediment whilst also stating that pelagic water already contains '*suspended particular [sic] matter that is naturally present in the water column*'. This amounts to reasoning, in essence, that there is no need to add solids or sediment to pelagic water since testing in such water, which already contains small quantities of suspended matter, already approximates the environmental conditions of large water bodies.

76. For these reasons, the third plea is rejected.

E - The fourth plea, alleging a breach of the principle of proportionality

Arguments of the parties

77. By its fourth plea in law the Appellant argues that the Contested Decision breaches the principle of proportionality.

78. This plea consists of two parts. By the first part of its fourth plea the Appellant argues that the Contested Decision is disproportionate insofar as it requires

persistence testing in fresh as well as in marine water. The Appellant argues that, if the Agency concludes that the Substance can be found in both fresh and marine water, '*it is freshwater as such that is most relevant for the water compartment testing*'.

79. Moreover, the Appellant also argues that '*a test in marine water would be sufficient to exclude the risk of persistency*'. Unless there is evidence that the Substance is less degradable in freshwater than in marine water, the additional study using freshwater is not necessary. This position is supported by a proposal for amendment of the Draft Decision submitted by the MSCA of the United Kingdom, according to which '*unless there is evidence to suggest that triclosan is less degradable in freshwater*' the additional freshwater study is not necessary.

80. The Appellant also argues that the Agency has failed to make clear the objective pursued by the freshwater test. In particular, it did not state what results it expects from the freshwater test and how they might differ from the marine water test. The need expressed in the Contested Decision to have '*a more robust basis for concluding on persistency of [the Substance]*' is not sufficient to justify the additional testing burden.

81. By the second part of its fourth plea the Appellant claims that the requirement to perform the persistence testing as pelagic test, rather than in surface water amended with suspended solids/sediment of 0.01 to 1 g/L dry weight, is disproportionate.

82. With regard to the necessity of the measure, the Appellant argues that the Agency has failed to demonstrate that a potential risk needs to be clarified. Moreover, the Appellant argues that the Agency failed to show that the required test would lead to improved risk management measures.

83. As regards whether the requested test is appropriate to achieve the objective pursued, the Appellant argues that the Agency has failed to demonstrate that the testing strategy required by the Contested Decision '*would better clarify the potential risk of persistency or have a more realistic possibility of leading to improved risk management measures than the testing strategy proposed by the Appellant*.'

84. Moreover, the Appellant argues, in essence, that the testing conditions prescribed are not environmentally relevant.

85. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

1. The first part of the fourth plea, alleging that the requirement to perform the persistence testing in freshwater is disproportionate

86. The Board of Appeal notes as a preliminary point that the Appellant requests the modification of the Contested Decision to allow the test to be performed in marine water (see paragraphs 23 and 29 to 32 above). The first part of the fourth plea must therefore be understood as alleging that the requirement to conduct persistence testing in freshwater is disproportionate.

87. The Board of Appeal recalls that the principle of proportionality, which is a general principle of European Union law, requires that European Union measures do not exceed the limits of what is appropriate and necessary in order to achieve the objectives legitimately pursued by the measure in question. When there is a choice between several appropriate measures recourse must be had to the least onerous,

and the disadvantages caused must not be disproportionate to the aims pursued (see Case C-15/10, *Etimine*, EU:C:2011:504, paragraph 124 and Case T-135/13, *Hitachi Chemical Europe and Others* v *ECHA*, EU:T:2015:253, paragraph 110; see also Case A-006-2014, *International Flavors & Fragrances*, Decision of the Board of Appeal of 27 October 2015, paragraph 72 and the previous decisions cited therein).

88. As regards the Appellant's argument that the Agency failed to make clear the objective pursued by the requested persistence testing in freshwater, the Board of Appeal notes that the Contested Decision explains that '*further information is required in order to enable the eMSCA to complete the evaluation of whether the substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB). The data for Triclosan in the chemical safety report contain bioconcentration factors in fish higher than 2000 and chronic NOECs or EC10s for algae and invertebrates below 10 µg/L. As a result, the [bioaccumulation and toxicity] criteria of Annex XIII of the REACH Regulation are met […]. The assessment strategy therefore focuses first on persistence of the registered substance.*' The Contested Decision therefore clearly states the objective of the persistence testing.

89. Moreover, as regards specifically the requirement to test the Substance in freshwater, in addition to marine water, the Contested Decision states as follows:

'*It can not be predicted beforehand, whether freshwater or seawater would be the critical compartment for persistence: The half-life in seawater is expected to be longer than in freshwater, but the [persistence] criterion for seawater (60 days) is also longer than for freshwater (40 days). Only if the results clearly show that based on a single environmental medium, the substance is very persistent (vP), no further testing would be needed for the second medium. In addition, results of tests in both freshwater and seawater will provide a more robust basis for concluding on persistency of Triclosan based on a weight of evidence approach if needed.'*

90. In light of the extracts quoted in paragraphs 88 and 89 above, the Board of Appeal finds that the Contested Decision indicates the objective pursued by the requested persistence testing in freshwater, namely to determine whether the Substance is persistent in freshwater.

91. The Appellant further argues that the Substance is more likely to be persistent in marine water than in fresh water. It therefore appears to take the view that testing in marine water would suffice to confirm or dispel the concerns relating to the Substance's persistence, and that testing in freshwater consequently goes beyond what is necessary to achieve the objective pursued by the measure in question.

92. In this regard, the Board of Appeal notes that the Appellant's argument is contradictory. The Appellant claims that '*a test in marine water would be sufficient to exclude the risk of persistency*', whilst also arguing that testing in marine water is less environmentally relevant than in freshwater (see paragraphs 78 and 79 above). It has requested to be allowed to conduct the test in marine water in the Notice of Appeal and in freshwater at the hearing (see paragraph 29 above). Moreover, the Appellant has asserted, but not demonstrated, that the Substance is more likely to be persistent in marine than in fresh water. As the Agency points out, the half-life of the Substance in marine water is likely to be longer than in freshwater but, in accordance with points (a) and (b) of Section 1.1.1 of Annex XIII, the half-life required for a finding of persistence is also longer in marine than in fresh water. In these circumstances, the Board of Appeal considers that it cannot be predicted in which type of water the Substance is more likely to be persistent.

93. The Board of Appeal recalls that, in accordance with Section 1.1.1 of Annex XIII, a substance is considered to be persistent if it fulfils the half-life condition set out for any of the environmental compartments mentioned (see paragraph 49 above). In

particular, the Substance will fulfil the conditions for persistence if its degradation half-life in marine water is higher than 60 days, or if its degradation half-life in fresh or estuarine water is higher than 40 days. The persistence testing required by the Contested Decision will not only determine if the Substance is persistent, but also contribute to the characterisation of the risk of persistence in the two compartments identified. In the present case, the risk management measures adopted, for example pursuant to the restriction and authorisation procedures under Titles VII and VIII of the REACH Regulation, may vary depending on whether the Substance is found to be persistent in freshwater, in marine water, or both. Given that the Substance is present in both of these compartments, and that there is evidence to show that it may be persistent in both marine and freshwater, there is a potential concern for persistence of the Substance in both compartments. Pursuant to the substance evaluation of triclosan and the objectives of substance evaluation, testing for persistence in both compartments is therefore justified.

94. The Board of Appeal observes furthermore that persistence testing takes a considerable amount of time, during which it will not be possible to conclude on the persistence of the Substance. As the Agency acknowledges, if testing in one compartment were to show that the Substance is very persistent, testing in the other compartment might be considered to be unnecessary as risk management measures would probably be applied to all compartments. However, it cannot be predicted in which type of water the Substance is more likely to be persistent nor if the Substance will prove to be very persistent in either compartment. If testing in the two types of water were conducted sequentially, the assessment of the Substance's persistence could be delayed by several years. Such a delay would jeopardise the attainment of the main objective of substance evaluation, namely to achieve a high level of protection of human health and the environment (see, to that effect, Case C-558/07, *S.P.C.M. and Others*, EU:C:2009:430, paragraph 45, and Case T-135/13, *Hitachi Chemical Europe and Others* v *ECHA*, EU:T:2015:253, paragraph 46; see also Case A-015-2014, *BASF*, Decision of the Board of Appeal of 28 June 2016, paragraph 52 and the previous decisions cited).

95. In addition, the Contested Decision states that '*[g]iven the fact that both the test set-up (i.e. climate conditioning, vessels etc.) and the chemical analysis (same substance, same analytical protocol and apparature) are the same for the test in freshwater and seawater, the eMSCA considered it appropriate and proportionate to perform both tests simultaneously. This will avoid unnecessary costs and undue delay, especially because similar tests may have to be repeated if the [Substance] proves not to be persistent and simulation testing may need to be performed for the metabolite methyl Triclosan*.' The Appellant has not raised any detailed arguments to challenge this statement.

96. For the reasons set out in paragraphs 88 to 95 above, the Board of Appeal rejects the Appellant's arguments that the requirement to perform the persistence testing in freshwater is disproportionate.

97. Finally, and for the sake of completeness, the Board of Appeal also rejects the Appellant's argument insofar as it can be understood as alleging that the requested testing in two types of water is not the least onerous measure to meet the objective pursued. It must be observed that, for the reasons stated in paragraphs 92 to 96 above, if testing was conducted in marine water only the objective pursued could not be met. Therefore, testing in marine water only cannot be considered to be a less onerous option within the meaning of the requirements of the principle of proportionality (see paragraph 87 above).

98. For these reasons, the first part of the fourth plea is rejected.

2. The second part of the fourth plea, alleging that the requirement to perform the persistence testing as a pelagic test is disproportionate

99. By the second part of its fourth plea the Appellant claims, in essence, that the requirement to perform the persistence testing as a pelagic test, rather than in surface water amended with suspended solids/sediment of 0.01 to 1 g/L dry weight, is disproportionate.

100. First, with regard to whether the measure in question is necessary, the Appellant argues that the Agency has failed to demonstrate that a potential risk needs to be clarified and that the required testing would lead to improved risk management measures.

101. The Board of Appeal recalls that, in order to demonstrate the necessity of a request for information in the context of the substance evaluation procedure, the Agency must be able to demonstrate that there is a potential risk to human health and the environment, that this risk needs to be clarified, and that the requested information has a realistic possibility of leading to improved risk management measures. If these conditions cannot be met the information requested would not meet real information needs for the protection of human health and the environment pursuant to substance evaluation (see Case A-005-2014, *Akzo Nobel Industrial Chemicals and Others*, Decision of the Board of Appeal of 23 September 2015, paragraph 73).

102. Concerning the existence of a potential risk which needs to be clarified, the Board of Appeal recalls that the identification of a potential risk is based on a combination of hazard and exposure information (see Case A-015-2014, *BASF SE*, Decision of the Board of Appeal of 28 June 2016, paragraph 58 and the previous decisions cited therein). In particular, as the Agency correctly points out, existing data – none of which are derived from studies in pelagic water – indicate that the Substance may be persistent, but the interpretation of the existing simulation tests is hampered by the formation of a high amount of bound residues preventing a definitive conclusion on the persistence of the Substance based on the existing studies alone (see paragraphs 43 to 45 above). Testing in pelagic water is therefore necessary to examine what will happen in a situation where bound residues do not play a significant role.

103. The Board of Appeal further notes that the information derived from the required testing, assessed together with the existing data, is expected to provide a definitive conclusion on the persistence of the Substance. This may lead, for example, to its identification as a substance of very high concern (hereinafter 'SVHC') under Article 57(d). In the event that the Substance is shown to be persistent improved risk management measures may be put in place, including potentially through the restriction process and/or the authorisation process pursuant to the REACH Regulation. The requested test therefore has a realistic possibility of leading to improved risk management measures.

104. In light of the reasons stated in paragraphs 102 and 103 above, the Appellant's argument that the Agency has failed to demonstrate that a potential risk needs to be clarified and that the required testing would lead to improved risk management measures must be rejected.

105. Second, the Appellant argues, in essence, that the measure in question is not appropriate to achieve the objective pursued because the testing conditions are not environmentally relevant. This argument overlaps with the Appellant's arguments under the first plea (see paragraphs 33 to 51 above) and must be rejected for the same reasons.

106. Third, the Appellant argues, in essence, that the contested measure is not appropriate to achieve the objective pursued because its own proposed testing strategy, namely testing surface water amended with suspended solids/sediment of 0.01 to 1 g/L dry weight rather than with pelagic water, '*would better clarify*' the concern than the strategy required by the Agency. However, the test to be applied to the assessment of the appropriateness of a measure is not whether the measure in question is the most appropriate to achieve an objective, but whether it is capable of achieving the objective in question (see, for example, Case T-368/11, *Polyelectrolyte Producers Group and Others* v *Commission*, EU:T:2013:53, paragraph 81). This argument therefore overlaps with the argument in the previous paragraph and must be rejected for the same reasons.

107. For these reasons, the second part of the Appellant's fourth plea cannot prosper and the fourth plea must be dismissed.

F - The fifth plea, alleging a breach of the principle of good administration

Arguments of the parties

108. By its fifth plea in law the Appellant argues that the Agency breached the principle of good administration by failing to conduct a proper legal and scientific review of the Draft Decision prepared by the eMSCA.

109. In the Appellant's view, the Agency was obliged to perform such a review by virtue of a statement to that effect contained in the '*ECHA Procedure on Substance Evaluation*' (PRO-0023.02, applicable at the time of the adoption of the Contested Decision), which states that the Agency '*aims at performing a scientific and legal consistency screening on the draft decision to ensure that the substance evaluation is based on sound and consistent judgement, and that requests for further information are consistent, scientifically robust and legally accurate*.' As the Agency did not consider the appropriateness of the alternative sediment testing strategy under OECD TG 309, nor explained why a comment from the UK MSCA concerning the fact that a test in marine water should be conducted as a first step, was not taken into account, its legal review of the Draft Decision was incomplete and inconsistent with the principle of good administration.

110. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

111. The right to sound administration is enshrined in Article 41 of the Charter of Fundamental Rights of the European Union, which provides inter alia that every person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions, bodies, offices and agencies of the Union. In accordance with the case-law, this right presupposes a duty of diligence which requires the competent institution to examine carefully and impartially all the relevant aspects of the individual case (see Case T-643/11, *Crown Equipment (Suzhou) and Crown Gabelstapler* v *Council*, EU:T:2014:1076, paragraph 46).

112. First, the Board of Appeal notes that the Appellant's arguments on the principle of good administration concerning the alternative water-sediment test overlap with the arguments raised in support of the other pleas regarding the request for persistence testing, and must be dismissed for the same reasons.

113. Second, concerning the Appellant's argument that the Agency failed to review the Contested Decision, the Board of Appeal observes that, even on the assumption that the right to a sound administration obliges the Agency to conduct a '*proper legal and scientific review*' of a draft decision, no illegality has been detected with regard to the requirement to perform the persistence testing. The Agency therefore could not be reproached for failing to conduct such a review even if it were indeed obliged to do so.

114. Third, the Appellant argues that the Agency failed to explain why a comment submitted by the MSCA of the United Kingdom together with a proposal for the amendment of the Draft Decision was not taken into account. In this regard, the Board of Appeal observes that the Contested Decision states '*[the United Kingdom MSCA] suggested to test seawater only, due to the expected slower biodegradation in seawater than in fresh water. As an alternative, they suggested to test seawater first before proceeding to freshwater if still considered necessary to confirm the persistence properties of Triclosan.*' The Contested Decision then goes on to reject this suggestion explicitly in the terms cited in paragraphs 89 and 95 above. The Appellant's argument is therefore unfounded as the views of the MSCA of the United Kingdom were clearly taken into account.

115. For these reasons, the Appellant's fifth plea is rejected.

II. The second request for information, concerning the enhanced developmental neurotoxicity study

116. The Appellant raises four pleas in law against the requirement to perform an enhanced developmental neurotoxicity study, namely breaches of (i) Article 47, (ii) the duty to state reasons, (iii) Article 25, and (iv) the principle of proportionality.

A - Admissibility

117. At the outset, it is necessary that the Board of Appeal should examine the admissibility of part of the form of order requested by the Intervener and of certain pieces of evidence which were put forward during the course of these proceedings.

1. Admissibility of the Intervener's request to amend the Contested Decision in order to minimise distress in animals

118. As an alternative to annulling the request for an enhanced developmental neurotoxicity study, the Intervener requests the Board of Appeal to amend the Contested Decision with the aim of minimising distress in animals (see paragraph 24, third indent, above).

119. According to Article 8(3) of the Rules of Procedure, an intervention shall be limited to supporting or opposing the remedy sought by one of the parties. It follows that an intervener must accept the proceedings before the Board of Appeal as it finds them at the time of the intervention (see, to that effect, the order of the General Court in Case T-673/13, *European Coalition to End Animal Experiments* v *ECHA*, EU:T:2015:167, paragraph 36; see also Case A-022-2013, *REACheck Solutions*, Decision of the Board of Appeal of 15 March 2016, paragraph 47).

120. As the Appellant, whom the Intervener supports, does not seek the amendment of the request for an enhanced developmental neurotoxicity study in the Contested Decision with the aim of minimising distress in animals, the Intervener's request to this effect must be rejected as inadmissible.

121. The Board of Appeal notes, however, that, as the Agency correctly points out, the Contested Decision does not prescribe the details of testing. When satisfying the information requirement the Appellant still has to apply the relevant provisions in the REACH Regulation and to abide by the applicable animal welfare rules, such as instruments transposing Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

2. Admissibility of certain pieces of evidence

122. The Appellant relies, amongst other evidence, on a study attached to the Notice of Appeal (M. Axelstad et al., *Triclosan exposure reduces thyroxine levels in pregnant and lactating rat dams and in directly exposed offspring*, Food and Chemical Toxicology 59 (2013), pp. 534-540; hereinafter the 'Axelstad (2013) study') that was allegedly not available to the Agency during the decision-making procedure. The Agency disputes the admissibility of this study as evidence in these appeal proceedings.

123. When examining whether information or evidence submitted in support of the Notice of Appeal that was not available to the Agency during the decision-making procedure leading to the adoption of the Contested Decision is admissible the Board of Appeal needs to ascertain whether such information or evidence supports new facts or is supporting facts already alleged during the Agency's decision-making procedure (see Case A-001-2012, *Dow Benelux*, Decision of the Board of Appeal of 19 June 2013, paragraph 46; Case A-006-2012, *Momentive Specialty Chemicals*, Decision of the Board of Appeal of 13 February 2014, paragraph 36; Case A-007-2012, *Italcementi*, Decision of the Board of Appeal of 25 September 2013, paragraph 51).

124. The Board of Appeal observes, in this regard, that the Axelstad (2013) study is intended to support the Appellant's allegation that the required enhanced developmental neurotoxicity study is unlikely to provide new information on potential neurotoxicity. The Appellant had already alleged this fact in its comments on the Draft Decision. The Appellant moreover claims, without being contradicted on this point by the Agency, that the findings in the Axelstad (2013) study were discussed at the meeting in which the MSC reached a unanimous agreement on the Contested Decision. In these circumstances, the Axelstad (2013) study constitutes admissible evidence.

125. The Board of Appeal also notes that the Appellant annexed to its observations on the Intervener's observations a document which was not submitted with the Notice of Appeal (E. Mihaich et al., *Triclosan and endocrine disrupting potential: A hypothesis-driven weight of evidence analysis*, Society of Environmental Toxicology and Chemistry, 2015; hereinafter the 'Mihaich (2015) report'). Without explicitly challenging the admissibility of this piece of evidence, the Agency suggests that the Board of Appeal should take into consideration the principles the Court of Justice of the European Union applies to assess the legality of a measure. That is, the legality of a measure should be assessed on the basis of the elements of fact and of law existing at the time when the measure was adopted. Information which did not exist at the time of the adoption of the Contested Decision should therefore be dismissed.

126. In accordance with Article 12(1) of the Rules of Procedure, no further evidence may be introduced after the first exchange of written pleadings unless the Board of Appeal decides that the delay in offering the evidence is duly justified.

127. The Mihaich (2015) report dates from 2015, which is after this appeal was filed. The Board of Appeal considers that it is possible that the delay in offering as evidence an experimental study carried out on a substance after the expiry of the deadline for submitting an appeal could be justified as the results of the study in question could constitute new facts which were not available at the time of the expiry of the deadline for filing an appeal.

128. The Board of Appeal observes however that the Mihaich (2015) report is not an experimental study, but rather the opinion of an expert formed on the basis of existing experimental studies, concerning the endocrine disruptive properties of the Substance. In the Appellant's words, '*while the methodology applied [in the Mihaich (2015) report] may be considered "new", the underlying data being assessed in [that report] is not. Notably, the analysis is limited to an assessment of studies that were already existing and available to ECHA at the time of the Contested Decision*.'

129. In these circumstances, the Board of Appeal considers that the Mihaich (2015) report constitutes the opinion of an expert, which should normally be produced in evidence upon filing a Notice of Appeal, in accordance with Article 6(1)(f) of the Rules of Procedure. Nothing prevented the Appellant from commissioning such an expert opinion in due time, which is to say before the expiry of the deadline for filing the appeal. The Board of Appeal therefore considers that the delay in offering the expert opinion in evidence is not justified by the mere fact that the expert in question had not yet formed his or her opinion at the time of filing the appeal.

130. The Mihaich (2015) report must therefore be dismissed as inadmissible evidence.

131. At the hearing the Agency produced three further studies intended to rebut the conclusions of the Mihaich (2015) report. However, as the Mihaich (2015) report constitutes inadmissible evidence and cannot therefore be taken into account by the Board of Appeal when deliberating on the present case, there is no need to decide on the admissibility of the three studies submitted by the Agency.

B - Preliminary observations

132. In their submissions concerning the request for the enhanced developmental neurotoxicity study the Appellant and the Intervener rely on evidence from a large number of studies and make a great number of detailed scientific arguments, which are largely a repetition of arguments raised, and evidence considered, during the substance evaluation process and the decision-making procedure. Before examining the Appellant's pleas concerning the second request for information, namely the enhanced developmental neurotoxicity study, the Board of Appeal considers it necessary to make the following preliminary observations.

133. Appeal proceedings, even with a technically qualified member being part of the Board of Appeal, are not an opportunity simply to reiterate the many, and sometimes abstruse, scientific points previously discussed and addressed during the course of substance evaluation. To do so would extend the scope of an appeal beyond all reasonable limits.

134. It must in particular be highlighted that where a ground for concern has been identified there is an uncertainty that may need to be addressed. Under substance evaluation it falls to the Agency to resolve that uncertainty through the exercise of its broad administrative discretion by the adoption of a decision. In the event of an appeal against that decision the Board of Appeal subsequently verifies whether that discretion was exercised properly. The fact that the Appellant does not share the Agency's view on a scientific point does not in itself suffice to demonstrate that the Agency's exercise of its administrative discretion was flawed. On its own, a difference of scientific opinion is not capable of calling into question the legality of a

contested decision (see, to that effect, Case A-004-2014, *Altair Chimica and Others*, Decision of the Board of Appeal of 9 September 2015, paragraph 54).

135. In the present case, moreover, the Agency states that it examined a large number of studies which are explicitly included in the bibliography attached to the Contested Decision. Yet more studies are included in the appendix to the Contested Decision which lists the studies submitted with the Appellant's comments on the Draft Decision. The Board of Appeal accepts that the Agency considered these studies, since it cannot be incumbent on the Agency to address, in a substance evaluation decision, every point contained in all existing or submitted studies under pain of committing a breach of the obligation to state reasons (see, to that effect and by analogy, Case T-17/12, *Hagenmeyer and Hahn* v *Commission*, EU:T:2014:234, paragraph 173 and the case-law cited) or an error of assessment (see, to that effect, for example, Case T-368/11, *Polyelectrolyte Producers Group and Others* v *Commission*, EU:T:2013:53, paragraph 31). Nor can the Agency be criticised for failing to address studies which are manifestly irrelevant, unimportant or clearly ancillary (see, to that effect and by analogy, C-521/09 P, *Elf Aquitaine* v *Commission*, EU:C:2011:620, paragraph 154 and the case-law cited). On appeal, the onus of establishing that the Agency's exercise of discretion was flawed rests, prima facie, on the Appellant.

136. The Board of Appeal will proceed to examine the pleas raised by the Appellant in light of these considerations.

C - The seventh and eight pleas, alleging breaches of Article 25 and of the principle of proportionality

Arguments of the parties

137. By its seventh and eight pleas, which will be examined together and before the sixth plea, the Appellant alleges that the Contested Decision breaches Article 25 and the principle of proportionality insofar as it requires it to perform an enhanced developmental neurotoxicity study.

138. In essence, the Appellant considers that the existing data in rats in combination with human clinical data do not warrant further animal testing for neurotoxicity or reproductive toxicity. The Appellant argues that the request to perform an enhanced developmental neurotoxicity study on rats would not provide '*scientifically meaningful results*' as the neurotoxicity and reproductive toxicity effects of the Substance can already be extrapolated from existing data.

139. In the Appellant's view, the Agency failed to demonstrate that the substance poses a potential risk which needs to be clarified in that the weight of evidence is not sufficient to identify a potential risk of endocrine disruption in humans. The Appellant, supported by the Intervener, argues on the contrary that the weight of the evidence available to the Agency supports the conclusion that the Substance has no effect on human thyroid function. It submitted the Mihaich (2015) report in support of this argument.

140. In addition, according to the Appellant, even if the requested study showed adverse effects on rats a definite conclusion on effects on humans could not be drawn from such a finding. The Appellant argues in essence that there is considerable evidence that the rat thyroid system differs from the human thyroid system. As a consequence, any observed suppression of thyroxine in rats following exposure to the Substance is not reliably predictive of the human thyroid response. The required testing will therefore fail to clarify whether the Substance effects the

functioning of the human thyroid and therefore is not tailored to real information needs.

141. In this regard, the Appellant also takes issue with the Contested Decision insofar as it states that '*unless it can be proven that the rat is an unsuitable model […], the results obtained from rats with regards [sic] to [thyroxine] reduction, cannot be discarded and should be considered relevant for human health risk assessment*'. In this regard, the Appellant alleges an unlawful inversion of the burden of proof, in that it should be incumbent on the Agency to prove that the rat model is relevant, and not vice versa. Unless the Agency can prove that the required testing can produce results relevant to humans the Appellant claims that the request is not tailored to real information needs.

142. As regards the additional elements of an extended one-generation reproductive toxicity study (hereinafter 'EOGRTS'), concerning the possible effects of a reduction of thyroxine levels in female rats on the brain development of their offspring, the Appellant argues that, whilst non-standard tests can be required under substance evaluation, their justification should be subject to particular scrutiny. The Appellant states that '*there are real concerns that the requested study will not produce scientifically valid or useful information, contrary to "real information needs"'*.

143. The Appellant further argues that the principle of proportionality requires the Agency to apply the weight-of-evidence approach in circumstances in which there is evidence from many sources. In this regard, the Appellant argues that the Agency '*inappropriately discounted the existing relevant evidence from human studies that [the Substance] does not affect thyroid [sic] in humans at relevant doses'*. Methodological shortcomings in certain studies, as alleged by the Agency, cannot be used as a reason to disregard those studies in a weight-of-evidence approach.

144. The Appellant also submits that there are existing studies available to the Agency, such as the Axelstad (2013) study, which show that the requested study is unlikely to show that the Substance causes adverse effects, but which the Agency neglected to assess.

145. As a result of failing to apply a weight-of-evidence approach in circumstances in which there was sufficient existing evidence to address the effects of the Substance on the development of offspring, the Agency therefore failed to tailor the information request to real information needs. This approach is also inconsistent with Section 1.2 of Annex XI, which provides that '*where sufficient weight of evidence for the presence or absence of a particular dangerous property is available, further testing on vertebrate animals for that property should be omitted*'. This is particularly relevant, according to the Appellant, in light of Article 25 and the considerable animal welfare implications of the requested study.

146. The Appellant alleges moreover that the Agency has failed to demonstrate a link between the required test and improved risk management measures because the Agency did not justify how the results of the required test would substantially lower the present derived no-effect level (hereinafter 'DNEL').

147. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

148. The principle of proportionality, which is a general principle of European Union law, requires that European Union measures do not exceed the limits of what is appropriate and necessary in order to achieve the objectives legitimately pursued by the measure in question. When there is a choice between several appropriate

measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (see paragraph 87 above).

149. The Board of Appeal observes that the Appellant's arguments concern the necessity of the request for an enhanced developmental neurotoxicity study and its appropriateness to achieve the objective pursued. The Board of Appeal will therefore limit its reasoning to these two aspects.

1. Necessity of the contested measure

150. In order to demonstrate the necessity of a request for information in the context of substance evaluation, the Agency must be able to demonstrate that there is a potential risk to human health and the environment, that this risk needs to be clarified, and that the requested information has a realistic possibility of leading to improved risk management measures. If these conditions cannot be met the information requested would not meet real information needs for the protection of human health and the environment pursuant to substance evaluation (see paragraph 101 above).

151. The Appellant argues that the Agency failed to demonstrate that the Substance poses a potential risk which needs to be clarified because the weight of evidence is not sufficient to identify a potential risk of endocrine disruption in humans.

152. The Appellant claims that the Agency should have applied a weight-of-evidence approach when assessing whether there is a potential risk. The Board of Appeal recalls that, in accordance with Annex XI, a weight-of-evidence approach can be used to adapt standard information requirements for registration purposes. The Agency is not however obliged to apply such an approach in the context of substance evaluation (see paragraph 64 above) provided that it correctly exercised its discretion, in particular by establishing the existence of a potential risk.

153. As regards the question of whether the Agency has established the existence of such a potential risk, the Board of Appeal observes that the Contested Decision refers to a wealth of information, including in vitro studies and in vivo studies on rats as well as in humans. Based on that information, the Agency reached the conclusion that the Substance poses a twofold potential risk to human health. The Agency considered that the Substance could potentially disrupt the sexual development of offspring (Section III.II.2.1.1 of the Contested Decision) and could potentially act as a thyroxine inhibitor in humans thereby causing adverse neurological effects in the offspring (Section III.II.2.1.2 of the Contested Decision).

154. At the outset, the Board of Appeal observes that all the arguments raised by the Appellant to dispute the necessity of the measure regard the second ground of concern, namely that the Substance could potentially act as a thyroxine inhibitor in humans and as a consequence cause adverse neurological effects in offspring. The Appellant raises no arguments against the first ground of concern, namely that the Substance could potentially disrupt the sexual development of offspring. The Appellant's claim concerning the lack of a concern underlying the requested enhanced neurotoxicity testing must therefore be rejected as unsubstantiated insofar as this measure aims to clarify the first ground of concern.

155. As regards the second ground of concern (thyroxine inhibition and neurotoxicity), the Board of Appeal observes, first, that the Appellant's arguments concerning the conclusions to be drawn from the available data amount, in essence, to stating that the Appellant does not agree with the conclusions reached by the Agency. The Appellant's argument therefore amounts to a difference in scientific opinion and is consequently ineffective (see paragraph 134 above).

156. Second, as regards the potential neurotoxic effects of the Substance on offspring the Appellant argues that the Axelstad (2013) study shows that the Substance '*is unlikely to present relevant adverse effects*'. However, it is also stated in the Axelstad (2013) study that '*there might be a need for further assessment of triclosan as a potential developmental neurotoxicant*'. In addition, the Agency argued during the course of these proceedings that the Axelstad (2013) study is not sufficient to dispel the concern that the Substance may affect the brain development of offspring by reducing the level of thyroxine in the mother. The Appellant has not, in this regard, established that the Agency was incorrect in the conclusions it reached, but rather that it disagrees with the Agency on its interpretation of the existing data. The Appellant's argument therefore cannot call into question the legality of the contested measure (see paragraph 134 above).

157. Third, the Appellant claims that the Agency's assessment of the necessity of the measure with regard to neurotoxicity is flawed insofar as it is based on the premise that the reduction of the levels of thyroxine observed in rats allows the conclusion to be drawn that the Substance poses a potential risk to human health. The Appellant argues, in essence, that the observed suppression of thyroxine in rats is not reliably predictive of the human response to exposure to the Substance. This argument overlaps with the Appellant's argument concerning whether the measure in question is appropriate to achieve the objective which it pursues (see paragraphs 163 to 165 below), and must be rejected for the same reasons.

158. For the reasons stated in paragraphs 151 to 157 above, the Board of Appeal rejects the Appellant's argument that the Agency did not establish the existence of a potential risk. Moreover, given the wide use made of the Substance, and the widespread possibility of exposure to it, this potential risk clearly needs to be clarified.

159. The Board of Appeal further notes that if the required enhanced developmental neurotoxicity testing shows that the Substance is an endocrine disruptor and/or affects the brain development of offspring, this is very likely to lead to the adoption of risk management measures, including as a consequence of its identification as a SVHC in accordance with Article 57. As a consequence, the Appellant's argument that the requested study has no realistic possibility of leading to improved risk management measures must be rejected.

160. For these reasons, the Board of Appeal rejects the Appellant's claim that the request to perform an enhanced developmental neurotoxicity study is unnecessary.

2. Appropriateness of the contested measure to achieve the objective pursued

161. The Appellant argues that results derived from testing on rats do not allow a conclusion to be reached as to the effects of the Substance in humans. This amounts, in effect, to arguing that the measure in question is not appropriate to achieve the objective pursued, which is one of the requirements of the principle of proportionality (see paragraph 87 above).

162. The objective of the request for an enhanced developmental neurotoxicity study is to clarify whether the Substance is an endocrine disruptor and whether it affects the brain development of offspring (see paragraph 153 above). As the Appellant challenges the Agency's assessment, and as the Contested Decision contains a number of arguments in that regard, it is incumbent on the Appellant to establish that testing on rats is not appropriate to achieve that objective.

163. In the present case, the Appellant has identified problems with extrapolating from results in rats to humans. The Agency also recognises these issues in the Contested

Decision, for example stating that '*[t]hese species differences could affect the importance of the timing of correct thyroid hormone levels during brain development in the different species*' and '*[w]hen extrapolating data from rats to humans for risk assessment purposes, it is important to keep in mind some important species differences*'. The Agency was therefore aware of the issues raised by the Appellant. However, the eMSCA and the Agency have examined the numerous comments made by the Appellant in this regard and justified, in the Contested Decision, the relevance of rat studies to the clarification of the potential risk to humans. For example, the Contested Decision states that '*together [the available test] results indicate that such a mechanism [increasing liver catabolism via the PXR/CAR pathway] of thyroid disruption could indeed be relevant for human risk assessment*'. The Contested Decision also states that '*because the differences between humans and rats in relation to the sensitivity of chemical effects on T4 clearance are qualitative rather than quantitative, the results obtained from rats with regard to T4 reduction, cannot be discarded and should be considered relevant for human health risk assessment*'.

164. The Board of Appeal therefore finds that it is clear from the Contested Decision and the submissions in the present case that the Agency has carefully considered the species differences between rats and humans in arriving at its conclusions. The Appellant's arguments are a repetition of arguments raised, and addressed, during the decision-making procedure and amount to a difference in scientific opinion. They must therefore be rejected as ineffective (see paragraph 134 above).

165. The Board of Appeal recognises however that there are challenges in conducting toxicity testing on vertebrate animals that will give dependable results on the effects of a given substance on humans. Extrapolating the results from one species to another is complex. The test methods requested in the Contested Decision (OECD TG 426 with relevant elements of OECD TG 443) are however the 'state of the art' at this point in time. Whilst the Board of Appeal accepts that there are differences in the response of rats and humans to exposure to the Substance, this is not sufficient to demonstrate that the requested study will not provide useful information on the effects of the Substance on exposed humans. The Appellant has also not suggested during these proceedings a suitable alternative to the requested study taking into account the inter-species differences. Its argument concerning the appropriateness of the rat model must therefore also be rejected as unfounded.

166. For these reasons, the Appellant's claim that the required enhanced neurotoxicity testing is not appropriate to achieve the objective pursued cannot succeed.

167. In light of the above, the eighth plea, alleging a breach of the principle of proportionality, must be rejected.

168. Moreover, as the Appellant's arguments concerning the necessity for the request for an enhanced developmental neurotoxicity study have been rejected, and as neither the Appellant nor the Intervener have put forward an alternative to vertebrate animal testing beyond the arguments concerning the necessity of that measure, the seventh plea, alleging a breach of Article 25, must also be rejected.

D - The sixth plea, alleging a breach of Article 47

Arguments of the parties

169. By its sixth plea, the Appellant, supported by the Intervener, alleges that the requirement to perform the enhanced developmental neurotoxicity study was adopted in breach of Article 47.

170. This plea consists of two parts, the first challenging the request for neurotoxicity testing in its entirety and the second the additional elements of an EOGRTS.

171. In support of the first part of this plea, the Appellant argues that the Agency breached Article 47 by failing to take into account submitted information which shows, first, that data derived from studies performed with rats are not relevant to humans, second, that the Substance does not affect the human thyroid function and, third, that the requested developmental neurotoxicity study is unlikely to show effects on the offspring.

172. By its first argument in support of the first part of this plea, namely that the Agency disregarded evidence showing that data derived from studies performed with rats are not relevant to the assessment of effects of the Substance in humans, the Appellant argues in essence that even if the study were to show that the Substance reduces the levels of thyroxine in rats and thereby affects the brain development of rat offspring, those results would not be indicative of a similar response and effect in humans.

173. Moreover, according to the Appellant, even if the human thyroid response to the Substance would be similar to the rat's, the weight of available clinical evidence shows that thyroxine suppression in humans during pregnancy is unlikely to have adverse effects on neurological development.

174. By its second argument in support of the first part of the sixth plea, namely that the Agency inappropriately discounted evidence that the Substance does not affect the thyroid in humans at relevant doses, the Appellant argues, in essence, that the existing evidence in humans supports the conclusion that the Substance does not affect human thyroid function at the relevant doses. Therefore, even if the requested developmental neurotoxicity test linked high doses of the Substance to neurological deficits in rat pups, the finding would have little or no relevance to human exposure to the Substance.

175. In this context the Appellant relies, in particular, on the following studies:

- M. Allmyr et al., *Human exposure to Triclosan via toothpaste does not change CYP3A4 activity or plasma concentrations of thyroid hormones*, Basic and Clinical Pharmacology and Toxicology 2009, 105(5), pp. 339-344 (hereinafter the 'Allmyr (2009) study').
- M. Cullinan et al., *Long term use of Triclosan toothpaste and thyroid function*, Science of the Total Environment 2012, 416, pp. 75-79 (hereinafter the 'Cullinan (2012) study').
- E. S. Koeppe et al., *Relationship between urinary Triclosan and paraben concentrations and serum thyroid measures in NHANES 2007-2008*, Science of the Total Environment 2013, 445-446, pp. 299-305 (hereinafter the 'Koeppe (2013) study').
- R. J. Witorsch, *Critical analysis of endocrine disruptive activity of Triclosan and its relevance to human exposure through the use of personal care products*, Crit Rev Toxicol 2014, pp. 1-21 (hereinafter the 'Witorsch (2014) study').
- K. Kapelari et al., *Pediatric reference intervals for thyroid hormone levels from birth to adulthood: a retrospective study*, BMC Endocrine Disorders 2008(8), p. 1 (hereinafter the 'Kapelari (2008) study').

176. By its third argument in support of the first part of the sixth plea, namely that the Agency failed to consider existing data demonstrating that the requested test is unlikely to show neurological effects in rat pups, the Appellant relies on the Axelstad (2013) study. According to the Appellant, that study indicates that a

reduction in thyroxine would not result in thyroid hormone-dependent biological effects on the development of rat offspring, even when pups are directly dosed with the Substance.

177. In support of the second part of the sixth plea, by which it challenges the request for additional elements from an EOGRTS, the Appellant argues that the Agency failed to take into account the information submitted by the Appellant according to which the Substance shows no reproductive toxicity. The Appellant argues, moreover, that the Agency failed to take into account the fact that certain study results were derived from studies performed with test material the purity of which was not reported and which may have been contaminated.

178. The Appellant argues that the Agency failed to take into account information on reproductive toxicity and points out that the Contested Decision states that *'[s]ince no actual results on weights or morphology of male reproductive organs was presented anywhere in IUCLID and since these endpoints were not investigated in the performed two-generation study, a proper evaluation of the effects of Triclosan on male reproductive disorders could not be performed'*. The Appellant claims that it submitted three relevant studies in the rat in which the gonads were analysed histopathologically and no effects were reported. The studies in question are the following:

- Ciba-Geigy, *90-day oral toxicity study in rats with FAT 80'023/H final report*, report number LBI project No. 22188, October 1983 (hereinafter the 'Ciba-Geigy (1983) study').
- Ciba-Geigy, *FAT 80'023 2-year oral administration to rats*, report number MIN 833005, 28 April 1986 (hereinafter the 'Ciba-Geigy (1986) study').
- Ciba-Geigy, *90-day subchronic dermal toxicity study in the rat with satellite group with irgasan DP300 (MRD-92-399)*, report number 139910B, 14 July 1994 (hereinafter the 'Ciba-Geigy (1994) study').

179. The Appellant moreover argues that it submitted a weight-of-evidence argument based on these three studies. The Appellant argues that the Agency did not acknowledge this weight-of-evidence argument and therefore failed to assess the relevance of the submitted data adequately.

180. As regards the allegation that the Agency based its findings on the potential endocrine disrupting properties of the Substance on studies which were conducted with testing material that was not fully characterised, the Appellant argues that the purity of the Substance is of particular importance because of the nature of the chemistry involved in the manufacturing process. Typically the manufacturing process requires several steps to remove toxicologically important contaminants from the final product. These contaminants have been shown to cause reproductive effects similar to those seen in the studies referred to in the Contested Decision.

181. In response to this argument, which was already put forward by the Appellant in its comments on the Draft Decision, the Contested Decision states that '*if Triclosan used for scientific testing was contaminated with dioxins, it appears likely that this Triclosan could also be used for other purposes, and therefore could be a source of human and environmental exposure*'. However, the Appellant argues that it is currently the only holder of a registration for the Substance under REACH, and that therefore the only quality of the Substance which the Agency should consider is that specified in the Appellant's registration dossier.

183. As the studies reported in the Appellant's registration dossier did not show effects on reproductive toxicity the Appellant takes the view that the information on testing material of unreported quality should not have been used to justify the need for testing.

184. The Intervener argues, inter alia, concerning the potential of the Substance to cause reproductive effects, that '*[the Agency] states that the main concern seems to be […] the estrogenic properties [of the Substance] and cites the results of a pubertal study in rats [T. E. Stoker et al., Triclosan exposure modulates estrogen-dependent responses in the female Wistar rat, Toxicological sciences 2010 (117), pp. 45-53; hereinafter the 'Stoker (2010) study'] in which the substance advanced the onset of vaginal opening and increased uterine weight at the highest dose of 150 mg/kg*'. The Intervener submits that in this study the females were killed at different stages of the oestrous cycle, which calls into question the significance of the observed changes in weight of the reproductive tissues.

185. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

1. The first part of the sixth plea, alleging that the requirement to perform a neurotoxicity study was adopted in breach of Article 47

186. By the first part of the sixth plea the Appellant argues that the Agency failed to take into account information showing that the effects of the Substance on rats is not relevant to the examination of its endocrine disrupting properties in humans, the Substance does not affect humans at the relevant doses and the required testing is unlikely to detect neurological effects on pups. The Appellant argues, moreover, that the Agency failed to take into account the information submitted by the Appellant demonstrating that the Substance shows no reproductive toxicity, and that the Agency failed to discount study results based on uncharacterised test material.

187. First, the Board of Appeal observes that the Appellant's arguments concerning the relevance of rat studies overlap with the arguments raised on the same point in support of the plea alleging a breach of proportionality. They must be dismissed for the same reasons (see paragraphs 163 to 165 above).

188. Second, as regards the Appellant's argument that the Agency failed to take into account relevant information showing that the Substance would not affect humans at the relevant doses, the Board of Appeal notes that three of the studies on which the Appellant relies (the Allmyr (2009) study, the Cullinan (2012) study and the Koeppe (2013) study) are included in the bibliography of studies considered by the Agency which is attached to the Contested Decision. The Appellant's claim that these studies were not taken into account must therefore be rejected (see paragraph 135 above).

189. The fourth study referred to by the Appellant, namely the Witorsch (2014) study, was published in July 2014, which is after the conclusion of the decision-making procedure and shortly before the formal adoption of the Contested Decision. This study was therefore not considered before the adoption of the Contested Decision.

190. The Board of Appeal observes that the Witorsch (2014) study has not been submitted in evidence during the course of these appeal proceedings. Therefore, Board of Appeal is not in a position to determine the veracity of the Appellant's assertion that the study was relevant to the assessment of the Substance.

191. In addition, the Witorsch (2014) study was not submitted nor available to the Agency during the course of the substance evaluation procedure and the Agency cannot therefore be reproached for not taking it into account. Moreover, even if this study did present further information on the Substance and had been available at the relevant time, there is no reason to consider that this information would have

been capable of affecting the Agency's assessment. The Agency has identified a potential risk based on a large number of studies (see paragraph 153 above). The Appellant does not argue that the Witorsch (2014) can assuage the Agency's concerns as regards the endocrine disrupting properties of the Substance, but merely claims that the study was not taken into account. Its argument must therefore be rejected.

192. Finally, the fifth study to which the Appellant refers, namely the Kapelari (2008) study, does not concern the Substance as such but merely lists paediatric reference intervals for thyroid hormone levels. Whilst this study, or other similar studies, may be relevant to the assessment of the results from the requested study it cannot affect the Agency's conclusion that the requested study is needed to clarify a potential risk.

193. For the reasons set out in paragraphs 188 to 192 above, the Board of Appeal rejects the Appellant's argument that the Agency failed to take into account relevant information showing that the Substance could not affect humans at the relevant doses.

194. Third, as regards the Appellant's line of argument that the Agency failed to take into account information showing that the required testing is unlikely to show neurological effects on pups, the Board of Appeal takes note of the Appellant's argument that the Axelstad (2013) study, which was not submitted to the Agency at the time of the decision-making procedure leading to the adoption of the Contested Decision, indicates that a reduction in thyroxine would not result in thyroid hormone-dependent biological effects on the development of rat offspring, even when pups are directly dosed with the Substance.

195. However, as the Agency convincingly explained during the course of these proceedings, the results of the Axelstad (2013) study are not such as to call into question the assessment reflected in the Contested Decision. The Agency states that the Axelstad (2013) study does not change its assessment because the study does not address the endpoints relevant to understanding the neurotoxic potential of the Substance as the Substance was administered directly to rat pups and this was only a preliminary study using very few animals per dose group. The focus of this preliminary study was on measuring the levels of thyroxine in the pup's plasma and not on assessing any reproductive or neurodevelopmental parameters. As a consequence, the Appellant's arguments on the Axelstad (2013) study must be dismissed.

196. Moreover, as regards the Appellant's line of argument that the Agency failed to take into account the information submitted by the Appellant according to which the Substance shows no reproductive toxicity across numerous animal studies, the Board of Appeal observes that those arguments constitute a repetition of arguments raised in the comments on the Draft Decision. It is clear from the Contested Decision and the many studies and reports mentioned in its bibliography that the Agency took the relevant information into account when performing its assessment. The Appellant's argument must therefore be dismissed.

197. Finally, as regards the Appellant's allegation that the Agency based its findings on studies conducted with samples of the Substance contaminated by impurities, the Board of Appeal observes that the Contested Decision states in this regard that '*[t]he eMSCA noted that the quality of the test material was probably not considered in a number of the performed toxicity studies. However, if Triclosan used for scientific testing was contaminated with dioxins, it appears likely that this Triclosan could also be used for other purposes, and therefore could be a source of human and environmental exposure. In the description of the Kumar et al. study in the [Draft Decision], it was already stated that Triclosan used in this study may have been contaminated, why relatively little emphasis was put on these results.*

Since no actual results on weights or morphology of male reproductive organs was presented anywhere in IUCLID and since these endpoints were not investigated in the performed two generation study, a proper evaluation on the effects of Triclosan on male reproductive disorders could not be performed.' It is evident from this citation that the Agency took into account the fact that some of the studies, and one in particular, were conducted on Triclosan of unknown purity and potentially contaminated with dioxins. The Agency has therefore justified in the Contested Decision why these data are relevant to its assessment. The Appellant has indicated that it disagrees with these findings but not shown how the Agency acted illegally in this regard. The Board of Appeal consequently finds that the studies on samples of the Substance that may have been contaminated by impurities are relevant information for the purposes of Article 47 and that the Agency committed no error in taking them into account in the evaluation of the Substance. Furthermore, although the Agency reached a different conclusion than the one suggested by the Appellant, it fully justified its findings in relation to these studies.

198. The Board of Appeal further observes that the substance evaluation process takes into account all information available to the Agency. Information from testing may be from new OECD Test Guidelines or old non-validated studies, Good Laboratory Practice (hereinafter 'GLP') accredited test houses or non-GLP laboratories, on well characterised substances or substances of different or unknown compositions. It is the task of the eMSCA and the Agency to evaluate all the data before them in arriving at their conclusions and to justify these conclusions accordingly, as they have in this case. The Board of Appeal notes, importantly, that the Agency has not used the studies mentioned in the previous paragraph to come to a conclusion as to the reproductive toxicity of the Substance. This information is rather part of the '*relevant information*' that led the Agency to conclude that there is a potential risk that needs to be clarified. Furthermore, the Board of Appeal also notes that the requested studies will presumably be conducted on non-contaminated samples of the Substance, at a GLP accredited test house, and following OECD test guidelines. The results of such tests should therefore have a realistic possibility of clarifying the potential concerns identified in the Contested Decision and discussed in these proceedings.

199. In light of the above, the Appellant's argument must be rejected and the first part of the sixth plea must be dismissed.

2. The second part of the sixth plea, alleging that the requirement for additional elements of an EOGRTS was adopted in breach of Article 47

200. By the second part of its sixth plea the Appellant challenges the request for information insofar as it requires additional elements from an EOGRTS. The Appellant contests the statement in the Contested Decision that '*[s]ince no actual results on weights or morphology of male reproductive organs was presented anywhere in [the Appellant's registration dossier] and since these endpoints were not investigated in the performed two-generation study, a proper evaluation on the effects of Triclosan on male reproductive disorders could not be performed*'. The Appellant argues that the Agency failed to take into account three studies in the Appellant's registration dossier which provided information on the effects of the Substance on male reproduction as well as a weight-of-evidence argument submitted by the Appellant.

201. This argument relates to the Ciba-Geigy (1983), the Ciba-Geigy (1986) and the Ciba-Geigy (1994) studies. The Board of Appeal observes, in this regard, that the Ciba-Geigy (1983) and the Ciba-Geigy (1986) studies are listed in the bibliography of the Contested Decision. The Ciba-Geigy (1994) study, on the other hand, is

mentioned in passing in the Appellant's submissions in the present case but does not appear in the list of studies submitted during the course of the substance evaluation, which is appended to the Contested Decision. None of these studies have been filed during the course of these appeal proceedings. It is therefore impossible for the Board of Appeal to determine whether they were '*relevant*' to the assessment within the meaning of Article 47. The Appellant's argument must therefore be rejected as unsubstantiated.

202. As regards the Appellant's allegation that the Agency failed to take into account its '*weight of evidence argument*' that the Substance does not affect male reproduction, the Board of Appeal recalls that the Agency is not obliged to adopt a weight-of-evidence approach to reach a conclusion regarding a particular property in the context of substance evaluation (see paragraph 64 above), the question being rather whether the Agency failed to take relevant information into account. In any event, the Appellant did not make such a specific argument. Insofar as it presented available information on the point, the Contested Decision rebuts the Appellant's comments. The Agency cannot be expected to rebut points that have not been specifically made by the Appellant. As a consequence, the argument cannot succeed.

203. For the reasons set out above, the second part of the sixth plea must be dismissed, as must the sixth plea in its entirety.

E - The ninth plea, alleging a breach of Article 130

Arguments of the parties

204. By its ninth plea in law, the Appellant, supported by the Intervener, submits that the Agency failed to provide an adequate scientific rationale to support its request for developmental neurotoxicity testing in rats to investigate neurotoxic developmental effects in humans.

205. The Appellant, in particular, criticises the Agency's response to its comments on the relevance of the results of studies on rats to investigate effects of the Substance on the human thyroid function. The Contested Decision states that '*[the Scientific Committee on Consumer Products] saw no reason to favor hamster data and disregard rat data in its evaluation of Triclosan, and the [Scientific Committee on Consumer Products] in their 2011 addendum did not want to discard the data obtained in rats. [… The Agency] concurred with the [Scientific Committee on Consumer Products], and found that the rat data are also relevant for this evaluation of Triclosan*'.

206. According to the Appellant, the fact that the Scientific Committee on Consumer Products (hereinafter the 'SCCP') has already conducted a separate assessment in another legislative context is not legally binding on the Agency and does not relieve it of the obligation to make its own separate assessment. The Agency should have explained in a clear and unequivocal fashion why it decided to give preference to testing on rats over testing on hamsters. The Appellant claims that the statement in the Contested Decision cited in the previous paragraph does not suffice to fulfil the requirement of the duty to state reasons, especially in light of the Appellant's comments.

207. Furthermore, the Appellant criticises the Contested Decision for stating that the Appellant '*[has] not documented that the rat is an irrelevant model to use for human risk assessment, but only states that the induction of phase II catabolism in rats may have no human relevance. In order to reject rat data, proof that these are of no relevance for humans is needed*'. According to the Appellant and the

Intervener, proving that a scientific model has no scientific relevance whatsoever is neither possible nor a reasonable or legal requirement.

208. The Intervener, moreover, argues that the Contested Decision is insufficiently reasoned as regards the claim that the Appellant's documentation *'is limited to the induction of phase II catabolism*', as it ignores many additional points raised by the Appellant.

209. With respect to reproductive toxicity, the Appellant submits that the Contested Decision does not state the reasons why the study by Axelstad et al. (2013) was not sufficient to cover the need for information, and why it considered studies in the published literature on testing materials of undetermined and questionable purity to be of equal weight and relevance to studies submitted in the IUCLID dossier.

210. The Agency argues that the Contested Decision is sufficiently reasoned.

Findings of the Board of Appeal

211. The Board of Appeal recalls that the statement of reasons of a decision must be appropriate to the act at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in question in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the courts to exercise their powers of review (see paragraph 71 above).

212. The Board of Appeal rejects the Appellant's argument that the Contested Decision is insufficiently reasoned with regard to the scientific rationale for requesting developmental neurotoxicity testing in rats to investigate neurotoxic developmental effects in humans. The Contested Decision includes the Agency's response to the Appellant's comments on the relevance of the rat model for investigating effects on the human thyroid function by referring to a document issued by the SCCP, '*[t]he eMSCA noted that the argument that the hamster is the most appropriate species for extrapolation to humans with regard to Triclosan, has previously been presented in a supplementary submission to the opinion on Triclosan by the Scientific Committee on Consumer Products (SCCP) from January 2009. Here the applicant asked the SCCP to further consider differences in kinetics between species, since Triclosan, in the form of conjugates, undergoes extensive enterohepatic recirculation in rats and in mice, but not in hamsters and humans. However, the SCCP saw no reason to favor hamster data and disregard rat data in its evaluation of Triclosan, and the SCCP in their 2011 addendum did not want to discard the data obtained in rats. The eMSCA concurred with the SCCP, and found that the rat data are also relevant for this evaluation Triclosan*.'

213. The Board of Appeal observes, in this regard, that the part of the Contested Decision cited in the previous paragraph summarises the conclusions reached in a related procedure concerning the Substance, albeit in a different forum, and those conclusions were known to the Appellant, who is the only registrant of the Substance. A decision may refer to other acts and, in particular, take note of the content of an earlier act, especially if it is connected (see Case C-119/97 P, *Ufex and Others* v *Commission*, EU:C:1999:116, paragraph 57) or if the concerned person has that act at its disposal (see, to that effect, Case T-62/98, *Volkswagen* v *Commission*, EU:T:2000:180, paragraph 302). Furthermore, the Agency states that it '*concurred with the SCCP*', that is it considered the relevant data and agreed with the conclusions reached.

214. In addition, the reference to the conclusions of the SCCP is not the only reason given in the Contested Decision for rejecting the Appellant's arguments on the

relevance of studies on rats (see, for example, the section cited at paragraph 163 above).

215. In light of the above, the Board of Appeal finds that the Contested Decision is adequately reasoned as regards the Agency's replies to the Appellant's comments on the relevance of the rat model. As a consequence, the Appellant's argument must be rejected.

216. The Board of Appeal further notes that the adequacy of the statement of reasons must be distinguished from the question of whether the reasoning is well founded, which is concerned with the substantive legality of the measure at issue (see Case C-280/08 P, *Deutsche Telekom* v *Commission*, EU:C:2010:603, paragraph 130). The Appellant's argument that proving that the rat model has no scientific relevance whatsoever is neither possible nor a reasonable or legal requirement concerns the substantive legality of the measure at issue and not the statement of reasons. The Appellant's argument must consequently be rejected.

217. It is furthermore important to bear in mind that the requirements of the duty to state reasons can be attenuated if the measure in question was adopted in circumstances known to the affected person which enable it to understand the scope of the measure (see Case C-417/11 P, *Council* v *Bamba*, EU:C:2012:718, paragraph 54). This is the case where a party was closely involved in the process by which a contested decision came about and is therefore aware of the reasons for which the administration adopted it (see, to this effect, Case T-387/09, *Applied Microengineering* v *Commission*, EU:T:2012:501, paragraph 67 and the case-law cited; see also Case A-004-2014, *Altair Chimica and Others*, Decision of the Board of Appeal of 9 September 2015, paragraph 130). The Appellant's involvement in the decision-making procedure, coupled with the reasoning in the Contested Decision, enables the Appellant to understand how the Agency has arrived at its conclusions. As a consequence, the Appellant's argument that the Contested Decision '*ignores many additional points raised by the Appellant*' with regard to the relevance of the rat model, and phase II catabolism in particular, must be rejected.

218. The Board of Appeal also rejects the Appellant's argument that the Contested Decision does not state the reasons why the Axelstad (2013) study is not sufficient to dispel the concern that the Substance may affect the brain development of offspring. The Agency cannot be obliged to state the reasons for finding that a study does not address the concern identified if it was not included in the information submitted on the Substance on which the Agency based the Contested Decision. Moreover, the Board of Appeal has already accepted the Agency's argument that the Axelstad (2013) study does not clarify the potential concern identified (see paragraphs 194 and 195 above). As a consequence, and in light of the case-law cited in paragraph 135 above, even if the Axelstad (2013) study had been available at the time of the assessment the Agency could not be criticised for not specifically referring to that study in the Contested Decision.

219. Finally, the Appellant argues that the Contested Decision fails to explain why the studies on triclosan using materials of undetermined and questionable purity where given equal weight and relevance to studies submitted in the Appellant's registration dossier. The Board of Appeal observes in this regard that, as is apparent from the section of the Contested Decision cited in paragraph 197 above, the Contested Decision did not in fact attribute to such studies equal weight and relevance as to the studies in the Appellant's registration dossier.

220. The Appellant's ninth plea must therefore be rejected.

III. The third request for information, concerning the fish sexual development test

Arguments of the parties

221. By its tenth plea in law the Appellant, supported by the Intervener, alleges that the request to perform a fish sexual development test breaches Article 25(1) and the principle of proportionality. It argues that the requested study is not necessary because existing information shows the absence of significant adverse endocrine-mediated effects on fish at concentrations that do not cause general toxicity.

222. According to the Appellant, several studies show that the Substance is not sufficiently potent to produce endocrine-mediated adverse effects in vivo. Hence, there is no evidence of serious adverse effects on fish that are linked to an endocrine mode of action. The studies to which the Appellant refers are:

- BASF SE, *Evaluation of reproductive toxicity to fathead minnow (Pimephales promelas) using a 21-d fish reproduction screen (EPA/600/R-01/067)*, unpublished report, 2012, Fort Environmental Laboratories, Inc. Report No CSCH01-00222 (hereinafter the 'BASF (2012) study');
- C. M. Foran et al., *Developmental evaluation of a potential non-steroidal estrogen: triclosan*, 2000 (50) Mar. Environ. Res., p. 153-156 (hereinafter the 'Foran (2000) study').

223. The requested study therefore leads to a duplication of results and the sacrifice of animals for the purpose of generating an unnecessary set of data, breaching Article 25(1). It also infringes the principle of proportionality because the Agency has not established the necessity for the test, as it is obliged to do.

224. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

225. It must be recalled once more that in order to demonstrate the necessity of a request for information in the context of substance evaluation, the Agency must be able to demonstrate that there is a potential risk to human health and the environment, that this risk needs to be clarified, and that the requested information has a realistic possibility of leading to improved risk management measures. If these conditions cannot be met the information requested would not meet real information needs for the protection of human health and the environment pursuant to substance evaluation (see paragraph 101 above).

226. The Appellant argues, in essence, that the Agency has not established the existence of a potential risk to human health and the environment. The Appellant relies in this regard on several studies which are included in the registration dossier for the Substance to show the absence of a potential risk.

227. The Board of Appeal observes, at the outset, that there is considerable environmental exposure to the Substance (see paragraph 44 above). Moreover, the Contested Decision clearly identifies the potential adverse effects of the Substance on fish:

'*In the ecotoxicologal studies on fish, Triclosan caused vitellogenin induction in one study [H. Ishibashi et al.,* Effects of triclosan on the early life stages and reproduction of medaka Oryzias latipes and induction of hepatic vitellogenin*, 2004 (67) Aquat. Toxicol., p. 167-179; hereinafter the 'Ishibashi (2004) study'] and a combination of vitellogenin mRNA induction and decreased sperm-counts in another*

study [S. Raut and R. Angus, Triclosan Has Endocrine-Disrupting Effects in Male Western Mosquitofish, Gambusia Affinis, *Environmental Toxicology and Chemistry 2010(29), pp. 1287-1291]. Vitellogenin- and vitellogenin mRNA induction in fish are associated with an estrogenic mode of action, where decreased sperm counts could also be caused by anti-androgens or systemic toxicity. Triclosan is regarded as a suspected ED in fish because vitellogenin- and vitellogenin mRNA induction informs about estrogenicity but the links to the observed adverse effects are not fully conclusive. The biological significance of the decreased sperm counts observed in one study with fish is not fully clear because the fertilization rate was not investigated and therefore the link to an adverse effect on reproduction was missing. Test data relating to any specific mode of action, including endocrine activity, was also absent in this study*.'

228. The Contested Decision therefore clearly identifies a potential risk and the possibility of endocrine-mediated adverse effects in fish, which could lead to the Substance being considered to be a SVHC and is of such importance that it needs to be clarified.

229. The Appellant argues, in essence, that the Agency failed to '*adequately consider*' the two studies cited in paragraph 222 above when coming to this conclusion. Insofar as this argument can be understood as alleging that the Agency failed to take the two studies at issue into account, it must be rejected. The Appellant put forward arguments based on those two studies in its comments on the Draft Decision on 23 April 2013. With regard to the BASF (2012) study, the Contested Decision states:

'*[T]he 21-day fish study (EPA/600/R-01/067) is almost equivalent to the OECD TG 229 using fathead minnow. It is well known that such at test at level 3 of the QECD conceptual framework for endocrine disrupters (OECD ED CE) cannot be used as a definitive test (i.e. such tests can only confirm endocrine activity in vivo but hardly be used definitively for providing evidence of such activity providing a plausible link to adverse effects). It is also well known that the fecundity parameter of OECD TG 229 (and EPA/600/R-01/067) has a very low statistical power implying that this response variable may have provide a high relative rate of false negatives. Besides the fact that the highest test concentration was below the requested divisor of 10-12 of 96-h LC5O in this study, the Biosense vitellogenin (VTG) kit was furthermore used with a LOQ (level of quantification) of a factor 20000 above the announced LOQ which made detection of normal male vitellogenin levels impossible. In conclusion there may be several reasons relating to deficiencies of the study (BASE SE, 2012a) which explains why no effect in the plasma vitellogenin concentration in males was observed after exposure to 13.5 µg/L of Triclosan. Even a 100-fold increase in serum VTG levels from background levels would not have been discovered in a study with such a poor VTG LOQ. Therefore the claim of the Registrant(s) that this study supports that no further ED related fish testing is needed is rejected. Thus the conclusion remains that further fish testing using OECD TG 234 is needed.*'

230. With regard to the Foran (2000) study, the Contested Decision states:

'*Japanese medaka fry (Oryzias latipes) (Foran et al., 2000) were exposed for 14 days beginning 2 days post-hatch to Triclosan (100, 10, 1 µg/l), 17β-estradiol (E2; 1 µg/l), or a solvent control (ethanol). Two months post-exposure, the phenotypic sex of each adult was assessed visually using sexually dimorphic fin shape and size. Triclosan treatment did not skew the sex ratio of animals grown to maturity. The 100 µg/l group containing 64% males was not significantly different from the 47% male ethanol-treated group. However, 1 µg/l E2 produced 92% females, which was significantly different than controls. As expected, males had significantly longer dorsal and anal fins than females in each treatment group. Among females, there*

were no differences in fin lengths between the treatment groups. Among males, animals treated with 100 µg/l Triclosan had longer dorsal and anal fins than those treated with 10 µg/l the measurements of both Triclosan-treated groups overlapped the measurements from control males. A slight increase in the length of the dorsal fin and anal fin could indicate weak anti-estrogenic or androgenic effect but the evidence in this study was not sufficient to determine if Triclosan acts as an endocrine disruptor to disrupt development of fish.'

231. It is clear from the sections of the Contested Decision cited in paragraphs 229 and 230 above that the Agency did take the two studies into account.

232. In addition, in so far as the Appellant's argument can be interpreted as meaning that the Appellant does not agree with the Agency's assessment, the Board of Appeal recalls that, on its own, a difference of scientific opinion is not capable of calling into question the legality of the Contested Decision (see paragraph 134 above).

233. In light of the above, the tenth plea must be rejected insofar as it alleges a breach of the principle of proportionality.

234. As regards the alleged breach of Article 25(1), the Board of Appeal observes that the Appellant's arguments concerning the necessity of the request for information have been rejected. The Appellant has not put forward any alternative to testing on vertebrate animals beyond the arguments raised to dispute the necessity of such testing. As a consequence, the tenth plea must also be rejected insofar as it alleges a breach of Article 25.

IV. The fourth request for information, concerning the request to submit available information on the effects of the Substance on the cardiovascular system

Arguments of the parties

235. By its eleventh, twelfth and thirteenth pleas in law, which the Board of Appeal will examine together, the Appellant alleges that the Contested Decision breaches the principle of proportionality, the duty to state reasons and the principle of good administration in so far as it requires it to submit available information on the effects of the Substance on the cardiovascular system.

236. The Appellant argues that the concern on which this request is based derives from a single study (G. Cherednichenko et al., *Triclosan impairs excitation-contraction coupling and Ca2+ dynamics in striated muscle*, Proc Natl Acad Sci U S A. 2012 Aug 28;109(35):14158-63 hereinafter the 'Cherednichenko (2012) study'). That study, it is alleged, has '*virtually no relevance for humans*' because it used artificially high levels of the Substance to which humans would never realistically be exposed, and used a route of exposure (intraperitoneal dosing) which maximises toxic effects but has '*little or no relevance*' to the human exposure situation (the main routes of human exposure being dermal and oral). In the Appellant's view, the request to submit available information on the effects of triclosan on the cardiovascular system is therefore disproportionate.

237. In addition, the Appellant argues that the Contested Decision breaches the duty to state reasons in that it does not address the Appellant's comments on the study in question and, in particular, its scientific relevance. In the Appellant's view, the fact that this request for information was first introduced in a proposal for amendment, i.e. at a late stage of the decision-making procedure, makes it '*even more important*' that the Agency should offer sufficient justification.

238. Finally, the Appellant argues that the Agency was obliged to scrutinise the proposal for amendment regarding the request to submit available information on the effects of triclosan on the cardiovascular system to determine whether it '*impose[s] an unjustified burden*' on the Appellant. By failing to do so, the Agency breached the principle of good administration.

239. The Agency submits that the Contested Decision is proportionate and adequately reasoned as regards the request at issue.

Findings of the Board of Appeal

240. The Board of Appeal observes that, contrary to the Agency's argument, the fact that the request for available information on cardiotoxicity to be submitted is less burdensome than the requirement to conduct a study does not mean that the Agency is excused from establishing the necessity of the request, and in particular the existence of a concern which needs to be clarified (see paragraphs 87 and 101 above).

241. The Board of Appeal observes that the only evidence of a concern regarding cardiotoxicity identified in the Contested Decision is the Cherednichenko (2012) study which showed a cardiotoxic effect of the Substance in rats. In that study the test animals were administered high doses of the Substance by means of intraperitoneal injections. The high doses used and the highly unusual route of administration mean that the evidence generated must be treated with considerable caution. On their own, the results of the study are too weak to justify a request for further information. Furthermore, in the absence of other evidence, which would presumably have been submitted and assessed during the course of the substance evaluation process, it is also not clear what '*available information*' the Appellant would consider beyond the Cherednichenko (2012) study which has already been considered by the Agency.

242. In light of the above, the Board of Appeal finds that the Agency has not established that the request for available information on cardiotoxicity is necessary. The eleventh plea must consequently be upheld and the Contested Decision annulled insofar as it requires available information on cardiotoxicity to be submitted

243. In these circumstances, the twelfth and thirteenth pleas need not be examined.

Refund of the appeal fee

244. In accordance with Article 10(4) of Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 107, 17.4.2008, p. 6; hereinafter the 'Fee Regulation'), the appeal fee shall be refunded if the decision is rectified in accordance with Article 93(1) or the appeal is decided in favour of an appellant.

245. That provision is silent, however, as regards the refund of the appeal fee in cases such as this in which the Contested Decision is annulled in part and the case is not remitted to the competent body of the Agency for re-evaluation with regard to the annulled requests for information in accordance with Article 93(3).

246. In the circumstances of the present case, the Board of Appeal considers that the appeal cannot be deemed to have been '*upheld*' within the meaning of Article 10(4) of the Fee Regulation, since the greater and most burdensome parts of the requirements of the Contested Decision have been upheld. Article 10(4) of the Fee

Regulation makes no provision for the refund of part of the appeal fee, and the choice before the Board of Appeal is therefore binary, a full refund or no refund.

247. This is consistent with the application of Article 10(4) of the Fee Regulation in cases in which a contested decision is rectified by the Executive Director under Article 93(1). If the Executive Director revokes a contested decision in its entirety within thirty days after the filing of an appeal, the case is closed and the appeal fee is refunded (see, for example, Case A-024-2015, *Elkem*, Decision of the Board of Appeal of 29 June 2016). By contrast, if a contested decision is only partially rectified within thirty days under Article 93(1) and proceedings before the Board of Appeal continue, the appeal fee is not refunded if the appeal is dismissed.

248. In light of the above, the Board of Appeal concludes that the appeal fee should not be refunded.

Effects of the Contested Decision

249. According to Article 91(2), an appeal has suspensive effect.

250. The Contested Decision, which is only partially annulled in the present appeal proceedings, required the registrant, now the Appellant, to submit the required information by 26 September 2016, which is two years and one week from the date of adoption of the Contested Decision. The Board of Appeal considers however that, because of the duration of the present appeal proceedings, the deadline set in the Contested Decision should be interpreted, in the light of the principle of suspensive effect laid down in Article 91(2), as if it referred to two years and seven days from the date of notification of the final decision of the Board of Appeal.

251. Consequently, the information required by the parts of the Contested Decision which are not annulled shall be submitted within two years and one week from the date of notification of this Decision of the Board of Appeal.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls Decision No SEV-D-2114285478-33-01/F, adopted by the European Chemicals Agency on 19 September 2014, insofar as it requires the Appellant to submit available information on the effects of Triclosan on the cardiovascular system;**
2. **Dismisses the appeal for the remainder;**
3. **Decides that the remaining information required by the Contested Decision shall be provided by 26 December 2018;**
4. **Decides that the appeal fee shall not be refunded.**

Mercedes ORTUÑO

Chairman of the Board of Appeal

Alen MOČILNIKAR

Registrar of the Board of Appeal